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## **Brazil**

### **Biotechnology - GE Plants and Animals**

#### **Brazilian Annual Biotechnology Production & Outlook**

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**Report Highlights:**

Brazil is now the second largest producer of plant biotech crops in the world. Area planted with biotech crops is estimated to increase by 20 percent in the upcoming 2010-11 crop year. The increase is mostly attributed to higher use of plant biotech corn due to the increase in approvals of new biotech corn events in Brazil and higher availability of subsidized credit for farmers. Post has also updated other sections of the report to reflect new information from trade and government sources.

**Section I. Executive Summary:**

Bilateral agricultural trade between Brazil and United States reached US\$ 3.4 billion in CY 2009, of which Brazil exported to the United States US\$ 3 billion and imported from the United States US\$ 400 million. This represents a drop of nearly 19 percent from 2008 record trade due to the impact of the world financial crisis.

United States agricultural exports to Brazil are primarily agricultural commodities required to meet local shortfalls. Brazil is a major producer and exporter of agricultural products, such as soybeans, cotton, sugar, cocoa, coffee, frozen concentrated orange juice, beef, poultry, pork, tobacco, hides and skins, fruits and nuts, fish products, and wood products. As a result, the United States and Brazil are often competitors in third markets, while the United States is a major destination for Brazil's exports of sugar, coffee, tobacco, orange juice, and wood products.

Brazil is responding to the world financial crisis and possible food shortages by increasing agricultural production. A record US\$ 64 billion in credit at subsidized interest rates was announced for the upcoming 2009-10 crop season (Oct 2010 – Sep 2011). According to commodity analysts, these policy measures are likely to contribute to the use of modern production technology such as biotech events in the next crop year. According to the Ministry of Science and Technology (MCT), Brazil is a major leader in agricultural biotech research, and is now the second largest plant biotech producer in the world, after the United States.

## Section II. Plant Biotechnology Trade and Production:

A major increase in the use of biotech crops is expected for the upcoming 2010/11 Brazilian crop year (Oct 2010 through Sep 2011) making Brazil the second largest user of plant biotechnology in the world after the United States. During 2010/11 crop year, post expects that biotech corn seeds will account for 55 percent of corn area (or 8 million hectares), 78 percent soybean area (or 19 million hectares), and 22 percent of cotton area (or 200,000 hectares). The increase in plant biotech crops is due to higher availability of subsidized credit to Brazilian producers, as part of the overall agricultural credit package for the 2010/11 crop year estimated at US\$ 64 billion, combined with a major increase in the use of biotech corn varieties that were recently approved in Brazil.

Brazil also has in the pipeline other plant biotech crops waiting for commercial approvals, mostly for sugar cane, dry edible beans, potatoes, papaya and eucalyptus. One notable decision this year was the withdrawal from CTNBio's agenda of Liberty Link rice from Bayer Crop Sciences.

As of July 2010, there are 21 genetically engineered crops approved in Brazil: 11 for corn, 6 for cotton and 4 for soybeans.

### Cotton

Crop	Trait Category	Applicant	Event	Trait Description	Uses within Brazil
Round Ready Cotton	Herbicide Tolerant Insect Resistant	Monsanto	MON 521 x MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Round Ready Cotton	Herbicide Tolerant Insect Resistant	Monsanto	MON 521 x MON 1445	Gossypium hirsutum L. Glyphosate Herbicide	Textile Fibers Food and Feed
Bollgard II Cotton	Insect Resistant	Monsanto	MON 15985	Gossypium hirsutum L.	Textile Fibers Food and Feed
Wide Strike Cotton	Insect Resistant Herbicide Tolerant	Dow AgroScience	281-24- 236/3006- 210-23	Gossypium hirsutum L. Herbicide glufosinate ammonium	Food and Feed
Liberty Link Cotton	Herbicide Tolerant	Bayer	LL Cotton 25	Gossypium hirsutum L. Glyphosate Herbicide Ammonium	Textile Fibers Food and Feed
Bolgard	Insect	Monsanto	BCE 531	Lepidoptera Order	Textile

Cotton	Resistant				Fibers Food and Feed
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### Corn

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant</b>	<b>Event</b>	<b>Trait Description</b>	<b>Uses within Brazil</b>
Corn Zea Mays	Herbicide Tolerant Insect Resistant	DuPont Brasil	TC 1507 x NK 603	Glyphosate Tolerant Insect Resistant	Food, Feed, Imports
Corn Zea Mays	Insect Resistant	Monsanto	MON 89034	Lepidoptera Resistant	Food, Feed, Imports
Corn Zea Mays	Insect Resistant	Syngenta	MIR 162	Lepidoptera Resistant	Food, feed, Imports
Corn Zea Mays	Herbicide Tolerant Insect Resistant	Monsanto	MON 810 x NK 603	Glyphosate Tolerant Lepidoptera Resistant	Food, Feed, Imports
Corn Zea Mays	Herbicide Tolerant Insect Resistant	Syngenta	BT 11 x GA 21	Glyphosate Tolerant Lepidoptera Resistant	Food, Feed, Imports
Corn Zea Mays	Herbicide Tolerant Insect Resistant	Dow AgroScience	Tc 1507 Herculex	Glyphosate ammonium Herbicide Tolerant	Food and Feed
Corn Zea Mays	Herbicide Tolerant	Syngenta	GA 21	Glyphosate Tolerant	Food and Feed
Corn Zea Mays	Herbicide Tolerant	Monsanto	Roundup Ready 2 NK 603	Glyphosate Tolerant	Food and Feed
Corn Zea Mays	Insect Resistant	Monsanto	MON 810 Guardian	Lepidoptera resistant	Food and Feed
Corn Zea Mays	Insect Resistant	Syngenta	Bt 11	Lepidoptera resistant	Food and Feed
Corn Zea Mays	Herbicide Tolerant	Bayer CropScience	Liberty Link T 25	Ammonium Glyphosate tolerant	Food and Feed

## Soybeans

<b>Crop</b>	<b>Trait Category</b>	<b>Applicant</b>	<b>Event</b>	<b>Trait Description</b>	<b>Uses within Brazil</b>
Soybeans	Herbicide Tolerant	Bayer	Liberty Link A 2704-12	Gluphosinate ammonium	Food and Feed
Soybeans	Herbicide Tolerant	Bayer	Liberty Link A 5547-127	Gluphosinate ammonium	Food and Feed
Soybeans	Herbicide Tolerant	BASF Embrapa	CV 127	Herbicide Tolerant Imidazolinone class	Food and Feed
Soybeans	Herbicide Tolerant	Monsanto (Monsoy)	Roundup Ready TTS-40-3-2	Glyphosate Herbicide Tolerant	Food and Feed

### Section III. Plant Biotechnology Policy: Regulatory Framework

The regulatory framework for agricultural biotechnology in Brazil is outlined in law 11,105 of 2005, altered by law 11,460 of 2007 and Decree Number 5,591 of 2006. There are two main governing bodies that regulates agricultural biotech in Brazil.

- a. The National Biosafety Council (CNBS, in Portuguese). This council falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socio-economic implications and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the Office of the President, CNBS is comprised of 11 cabinet ministers and needs a minimum quorum of 6 ministers to approve any relevant issue.
- a. The National Technical Commission of Biosafety (CTNBio, in Portuguese) was initially established in 1995 under the first Brazilian Biosafety law (Law # 8,974). Under the current law, CTNBio was expanded from 18 to 27 members to include official representatives from 9 ministries of the federal government, 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area), and 6 other specialists from other areas such as consumer defense and family farming.

Members of CTNBio are elected for two years with a possibility of being reelected for an additional two years. CTNBio is under the Ministry of Science and Technology. All technical related issues are debated and approved under CTNBio. Imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis. For additional information on CTNBio, please see GAIN BR 5632.

Law 11,460 of March 21, 2007, changed article 11 of law 11,105 of March 24, 2005 and established that a simple majority of votes is needed out 27 total voters on CTNBio's board to approve new biotech products.

On June 18, 2008 the National Biosafety Council (CNBS) decided that it will only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian Biotech Law. CNBS will not evaluate technical decisions on biotech events that are approved by the National Technical Commission of Biosafety (CTNBio). The Council considers all approvals of biotech events by CTNBio as conclusive. This important decision, along with the change in majority voting, eliminates a major barrier for approval of biotech events in Brazil.

### **International Organizations**

Issues related to the Cartagena Protocol, CODEX ALIMENTARIUS, OIE and IPCC are handled in Brazil under inter-ministerial committees and negotiated in international forums by the Ministry of External Relations (MRE).

### **Cartagena Protocol:**

Brazil ratified in November of 2003 the United Nations Cartagena Protocol on Biosafety (under the UN Convention on Biological Diversity). With few exceptions, the Government of Brazil (GOB) is supportive of the positions advocated by the U.S. Government regarding the liability and redress provisions under the supplementary agreement to the Cartagena Biosafety Protocol. One notable exception is that the Brazilian Government considers the provisions regarding treatment of non-parties to be closed already. The GOB is also opposed to strict liability, but agrees to use a narrow definition of damage and supports the idea of a limited narrow definition of operator. The GOB is also opposed to the mandatory use of insurance or other financial instruments for the shipment of living modified organisms (LMOs).

### **Product Authorizations**

In Brazil, a technology provider must file an application for approval to sell agricultural biotech products with CTNBio. A company must file a single application for each biotech event. CTNBio will evaluate the need for any further environmental impact studies. After the approval of CTNBio, three other ministries have an important role in the registration process:

- a. Ministry of Agriculture, Livestock, and Food Supply (MAPA) for products used in agriculture, livestock, and agribusiness (processing);
- b. Ministry of Health, regarding use of products for humans and pharmaceutical uses; and,

- c. Ministry of Environment for products that require registration and inspection for use in the natural ecosystem.

### **Field Testing**

Field-testing of biotech crops is allowed in Brazil, but CTNBio must previously approve this research. The technology provider must obtain from CTNBio a Certificate of Quality in Bio Safety (CQB) to perform field-testing.

### **Coexistence of biotech and non-biotech crops**

There is no national policy in place regarding the coexistence of biotech and non-biotech crops in Brazil. Law 11,105 of March 2005 established the legal framework under which biotech crops can be produced and marketed in Brazil. Conventional or non-biotech crops are produced throughout the country with agricultural zoning and environmental limitations mostly applicable in the Amazon region.

Law 9,456 of April 25, 1997, called Plant Variety Protection law establishes the legal framework for registration of both biotech and non-biotech seeds, but the law does not favor one over the other.

Decree 2,366 of November 5, 1997, established the National Plant Varieties Protection Service under the Ministry of Agriculture, Livestock, and Food Supply (MAPA) and regulates the registration of biotech and non-biotech seeds.

### **Intellectual Property Rights (IPR)**

The new Biosafety Law, which provides a clear regulatory framework for the research and marketing of new biotechnology crops in the country, has encouraged Brazil's federal government to embrace and protect new technologies that benefit agriculture.

Multinationals companies, such as MONSANTO, SYNGENTA and BASF's, have licensing agreements with EMBRAPA (the Brazilian Agriculture and Livestock Research Enterprise, linked to the Ministry of Agriculture, Livestock, and Food Supply (MAPA) to develop plant biotech crops, mostly for soybeans, corn and cotton.

In general, technology providers negotiate at the beginning of the new crop year payment agreements with individual Brazilian states and farmer associations to collect royalty fees. Monsanto also pursues an export-licensing scheme to collect royalties on soybean and product shipments at ports of destination in countries where Monsanto has a patent on the RR soybean technology.

## **Labeling**

On April 24, 2003 the President of Brazil published in Brazil's Federal Register (Diario Oficial) Executive Order number 4,680/03 establishing a tolerance limit of **one percent** for food and food ingredients destined for human or animal consumption containing or being produced through biotech events. The Executive Order also declared that consumers need to be informed of the biotech nature of the product.

On December 26, 2003 the Ministry of Justice published in Brazil's Diario Oficial, Directive Number 2,658/03 approving the regulations for the use of the transgenic logo. It applies for biotech products for either human or animal consumption with biotech content above one percent. The requirement became effective March 27, 2004.

On April 2, 2004, the Civil Cabinet of the Presidency published Normative Instruction Number 1, signed by 4 cabinet ministers (Civil Cabinet, Justice, Agriculture, and Health) that established the conditions by which Directive 2,658/03 will enforce the labeling of products containing biotech events above the one percent limit. In addition to the federal agencies, Normative Instruction Number 1 also authorizes the state and municipal consumer defense officials to enforce the new labeling requirements.

### **Section IV. Plant Biotechnology Marketing Issues:**

Acceptance of biotech crops in Brazil is strong among producers. According to the Brazilian Farm Bureau (CNA), the latest full survey among Brazilian farmers dated from 2001 showed an 80 percent acceptance rate of biotech crops.

However, acceptance is low among meat processors and the food processing industry. These groups fear the marketing campaign against their products sponsored by Greenpeace and other environmental and consumer groups. Although, tests conducted by Greenpeace showed a minimum of biotech residues in several consumer ready products, Large Brazilian retailers also are reluctant to accept biotech products, especially the French-owned hypermarkets.

Reliable information about consumer acceptance of biotech products in Brazil is currently not available. In general, Brazilian consumers are disengaged from the biotechnology debate as they are more concerned about price, quality and the date of validity of their foods. However, a small number of consumers more oriented towards organic agriculture and sustainable production methods avoid plant biotech products.

There is a marketing campaign "Brazil Better without Transgenic" against the use of biotech crops in Brazil sponsored by Greenpeace and supported by certain environmental and consumer groups, including government officials within the Ministry of Environment, some political parties, the Catholic

Church, and the Landless Movement. The campaign against plant biotech products in Brazil is more effective among large retailers and food processors than Brazilian consumers in general.

### **Section V. Plant Biotechnology Capacity Building and Outreach:**

Post has developed and implemented the following three major outreach activities over the past six years:

1. Biotechnology Workshop, August 20-21, 2002 for a select group of Brazilian scientists from various ministries, universities, and scientific foundations;
2. Brazilian Congressional Visit to the United States in 2004 with representatives from select Brazilian NGOs and institutes;
3. Brazilian Corn Growers Visit in 2008 to the United States with selected representatives from the House Agricultural Committee.

### **Section VI. Animal Biotechnology:**

The National Technical Commission of Biosafety (CTNBio) issued on April 27, 2009 Normative Resolution Number 7 which regulates the development, commercial use and/or import of genetically engineered animals and their release into the environment. Regulation regarding contention was previously issued on November 27, 2007 under Normative Resolution Number 2. Both regulations are available in English at <http://www.ctnbio.gov.br>

Currently, the majority of the work performed for genetically modified animals is conducted by government institutions, such as public universities and centers for disease control using imported GM animals for research on specific diseases. All genetically modified animals or products from these animals to be imported into Brazil must be approved by CTNBio.

There are no products currently in the market derived from GM animals. Animals or products derived from genetically modified animals intended for commercial production are still in the research stage mostly conducted by Brazil's Agricultural Research Service (EMBRAPA), linked to the Ministry of Agriculture, an agency similar to the ARS-USDA system in the United States. Current research is mostly targeted at dairy cattle and other smaller animals. More information on GM animal research can be found at Embrapa's Center for Genetics and Biotechnology Research (CENARGEN) home page <http://www.cenargen.embrapa.br/>

Because this new technology is only at the research stage in Brazil, there have not been any studies regarding public perception of products from GM animals. However, as research advances, it is expected that the NGOs will launch campaigns against GM animals and products. For labeling of GM animals, please see section on Labeling.